

1. A process for the preparation of an orally administrable calcium composition, said process comprising the steps of:

(i) obtaining a physiologically tolerable particulate calcium compound having a mean particle size in the range 3 to 40 μ m, having a crystalline structure and having a surface area of 0.1 to 1.2 m²/g;

(ii) mixing said calcium compound with a water-soluble diluent and an aqueous solution of a water soluble binder in a fluid bed granulation apparatus and drying the resulting mixture to produce a first granulate;

(iii) optionally mixing said first granulate with one or more further components to produce a second granulate; and

(iv) optionally compressing said first or second granulate to form tablets.

2. A process as claimed in claim 1 wherein said calcium compound is selected from calcium carbonate, calcium lactate, calcium gluconate, calcium citrate, calcium glycerophosphate, calcium phosphate, calcium hydrogen phosphate, calcium glucuronate, calcium aspartate, calcium glucoheptonate and mixtures of two or more thereof.

3. A process as claimed in claim 1 wherein said calcium compound is calcium carbonate.

~~4. A process as claimed in any one of claims 1 to 3 wherein said calcium compound makes up 68 to 80% wt. of said first granulate.~~

5. A process as claimed in any one of claims 1 to 4 wherein said calcium compound makes up 60 to 95% wt. of

Sub A' → said second granulate.

5 6. A process as claimed in any one of claims 1 to 5 wherein in step (i) the same material is used as said diluent and as said binder.

10 7. A process as claimed in any one of claims 1 to 6 wherein said water-soluble diluent comprises at least one sweetener.

15 8. A process as claimed in claim 7 wherein said sweetener is selected from sorbitol, xylitol, isomalt, mannitol, sucrose, fructose, maltodextrin, inulin and oligofructose.

20 Sub A2 → 9. A process as claimed in any one of claims 1 to 8 wherein said water-soluble diluent makes up 70 to 96% wt. of the total weight of said water-soluble diluent and said water-soluble binder in said first granulate.

25 10. A process as claimed in any one of claims 1 to 9 wherein said water-soluble binder is selected from celluloses, polysaccharides, maltodextrin, inulin and polyvinylpyrrolidone.

30 11. A process as claimed in any one of claims 1 to 10 wherein said water-soluble binder is a polyvinylpyrrolidone

35 12. A process as claimed in any of claims 1 to 11 wherein said first granulate has a particle size distribution of $D(V, 0.1) = 15-21 \mu\text{m}$, $D(V, 0.5) = 70-120 \mu\text{m}$ and $D(V, 0.9) = 190-330 \mu\text{m}$.

40 13. A process as claimed in any one of claims 1 to 12 wherein a said further component is mixed with said first granulate, said further component being selected

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Sub A2
from: vitamin B₆, vitamin K, vitamin C, vitamin D,
isoflavones, inulin, and oligofructose and mixtures of
two or more thereof.

5 14. A process as claimed in any one of claims 1 to 13
wherein in step (ii) said calcium compound is also mixed
with isoflavones.

10 15. A granulate comprising a fluid bed granulation
granulate product of a physiologically tolerable calcium
compound, a water-soluble binder and a water-soluble
diluent, said calcium compound having a mean particle
size in the range 3 to 40 μ m, having a crystalline
structure and having a surface area of 0.1 to 1.2 m²/g.

15 16. A granulate as claimed in claim 15 further
comprising a lubricant.

20 17. A granulate as claimed in either of claims 15 and
16 wherein said calcium compound is selected from
calcium carbonate, calcium lactate, calcium gluconate,
calcium citrate, calcium glycerophosphate, calcium
phosphate, calcium hydrogen phosphate, calcium
glucuronate, calcium aspartate, calcium glucoheptonate
25 and mixtures of two or more thereof.

30 18. A granulate as claimed in any one of claims 15 to
17 said diluent is a sweetener selected from sorbitol,
xylitol, mannitol, sucrose, fructose, maltodextrin,
inulin and oligofructose.

35 19. A granulate as claimed in any one of claims 15 to
18 wherein said water-soluble binder is selected from
celluloses, polysaccharides, maltodextrin, inulin and
polyvinylpyrrolidone.

20. A granulate as claimed in any one of claims 15 to

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19 comprising a further component selected from: vitamin B₆, vitamin K, vitamin C, vitamin D, isoflavones, inulin, and oligofructose and mixtures of two or more thereof.

- 5 21. A tablet comprising a compressed granulate as claimed in any one of claims 15 to 20 containing: calcium carbonate; vitamin D₃; a lubricant; citric acid; and an oligosaccharide.

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